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January 21, 2020

Stan Barone
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460-0001

Re: N-Methylpyrrolidone (NMP), Draft TSCA Risk Evaluation, Docket ID: EPA-HQ-OPPT-2019-0236

Dear Dr. Barone,

The National Tribal Toxics Council (NTTC) appreciates the opportunity to provide comments on the N-Methylpyrrolidone (NMP) Draft Risk Evaluation under TSCA. As an EPA Tribal Partnership Group (TPG), supported by the EPA Office of Pollution Prevention and Toxics (OPPT), NTTC works on issues related to chemical safety, toxic chemicals, and pollution prevention for Indigenous people of the U.S. Through this partnership, we assist OPPT with education and outreach to tribes and, in turn, educate and inform EPA on the effects of chemicals and pollution upon tribal people.

NMP is found in a wide variety of commercial products, including paints, paint and coating removers, adhesives, solvents, reagents, sealers, inks, and grouts. It is also widely used in the electronics, petrochemical, and chemical manufacturing industries, as well as in lithium ion battery and semiconductor manufacturing. According to the EPA, over 160 million pounds of NMP were manufactured and/or imported in the USA in 2015 and global demand for NMP is expected to increase. Exposure to NMP is associated with fetal development problems, including low birth weight, birth defects, and stillbirth. NMP can also cause endocrine disruption, developmental toxicity, liver and kidney toxicity, reproductive toxicity, and neurotoxicity. In early 2017, the EPA proposed a rule to restrict most uses of NMP in paint and coating removers, but has not finalized this rule.

EPA released the draft risk evaluation for NMP in November 2019. The purpose of risk evaluations under the Toxic Substances Control Act (TSCA) is to determine whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use, including an unreasonable risk to any relevant potentially exposed or susceptible subpopulations. In this draft risk evaluation, EPA does not make an overall unreasonable risk determination for NMP but has instead made individual risk determinations for dozens of conditions of use. By not making an overall unreasonable risk determination, EPA has left tribal populations unprotected from this dangerous chemical that clearly poses risks to human health and the environment. NTTC is concerned that due to EPA's underestimation of the risks of NMP, it will not be adequately regulated during the risk management stage of the risk assessment process.

Based on our initial review of the draft risk evaluation, NTTC is concerned that EPA has again left out tribal populations' exposures to a toxic chemical and the risks they face have not been adequately evaluated. We take this opportunity to make 5 principal points in this comment letter that lead to this conclusion:

1. Disposal is a condition of use.
2. Tribes are a potentially exposed subpopulation.
3. These exposures are not covered by other federal Environmental Statutes and should be evaluated.
 - a. General population
 - b. Worker population
4. Risks from aggregate and cumulative exposures should be evaluated.
5. Legacy use must be included.

1. Disposal is a condition of use.

Recently, the Ninth Circuit Court of Appeals affirmed that "TSCA's definition of 'conditions of use' clearly includes "spills, leaks, and other uncontrolled discharges" from landfills, Superfund sites, and other disposal sites. EPA's Science Advisory Committee on Chemicals (SACC) similarly noted in its report on the 1,4-dioxane and HBCD draft risk evaluations that the EPA failed to consider releases associated with disposal. However, despite the explicit inclusion of disposal as a condition of use in TSCA and the Ninth Circuit's decision, risks associated with disposal-related releases are not evaluated for this Draft Risk Evaluation, just like they were not evaluated for Methylene Chloride and HBCD. On page 45 of the Draft Risk Evaluation, the EPA states that "EPA did not include [exposure] pathways under programs of other environmental statutes, administered by EPA, for which long-standing regulatory and analytical processes already exist" and this includes disposal.

In order to make an accurate risk characterization of tribal communities, EPA needs to consider releases of NMP from landfills as well as any other disposal facility, such as a transfer station or recovery facility. As NTTC has described in detail in previous comment letters, the disposal circumstances on tribal lands are different from those of urban areas. All products (commercial

and consumer) containing NMP will eventually be disposed in a landfill or other disposal site and, in the case of many tribal and rural communities, the disposal site may be in close proximity to residents, may be unlined, may be open access, and may include open burning as a management practice, all of which present multiple exposure pathways and routes for intake and uptake. Native Americans are more highly exposed to contaminants with environmental fate and transport than other populations, and in unique ways, because their lifeways revolve around environmental activities for dietary sustenance, socio-cultural activities, ceremonial and spiritual purposes, recreation, and general well-being. Tribal lifeways are not a choice and there is no alternative to them for the over 6.5 million Native Americans across the USA. Tribal lifeways can lead to chronic exposures to toxins in the environment, due to the longer duration and higher frequency of exposures tribal people may experience, as well as the higher cumulative dose from multiple exposure pathways. As disposal is the main route contaminants enter the environment, it is unacceptable to exclude disposal, and the resulting exposures to toxic chemicals like NMP, from consideration. Disposal is a major exposure pathway for NMP, with well over 7 million pounds of NMP a year entering the environment via land disposal (page 30). Additionally, NMP is not regulated as hazardous waste under RCRA, which means NMP is disposed in landfills and other disposal facilities that may not be designed as sanitary landfills, may lack performance standards, and may not be subject to federal or delegated state enforcement. NTTC urges EPA to evaluate the risks associated with disposal-related releases of NMP into the environment.

EPA is mandated by TSCA to determine whether the disposal of toxic chemicals presents unreasonable risk to human health and/or the environment. NTTC strongly urges that environmental release from waste management sites, including transfer sites, C&D sites, materials recovery facilities, and landfills be evaluated in the light of unlined facilities with resulting leachate subsurface flow, ponded water, direct surface water and snowmelt runoff, ambient emissions from uncovered disposal areas, and untreated waste burning emissions. A large portion of such sites have open public access, as well as proximate general populations, unprotected workers, and occupational bystanders. In terms of duration, tribal communities tend to have tribal workers who also live proximate to the site, and the diet, drinking water, and activities of they and the full community are dependent on the local, proximate environment as well. NTTC has in previous comment letters informed EPA in detail about the unique characteristics of disposal sites on tribal lands and in tribal communities and we are able and willing to provide extensive photographic and narrative evidence that exposure through disposal is very likely for tribal people.

2. Tribes are a potentially exposed subpopulation.

Tribes must be considered as a potentially exposed subpopulation under TSCA. Tribes have unique lifeways that place them at different risk due to longer exposure duration via multiple exposure pathways not experienced by the general population. For example, these lifeways include differences in:

1. Diet, such as significantly higher consumption of fish and other aquatic life that is typically locally caught;

2. Housing, which tends to be more often substandard, contain older household furniture and products, lack garages (resulting in product storage inside the home), and be associated with dirt yards and unpaved roads;
3. Worker safety protocols, which tend to be less stringently practiced due to multiple small businesses, self-employment, and do-it-yourself practices, as well as remote access locations unvisited by OSHA;
4. Water use for:
 - Drinking, which can be from untreated and unregulated small systems (less than 15 homes), including well water and surface haul water
 - Hygienic use, through daily steam baths
 - Ceremonial use through sweat lodges
 - Multiple artisanal activities (e.g. reed harvesting, mouthing, weaving);
 - Subsistence activities (e.g. hunting, gathering, fishing, preparing)
 - Recreational activities (swimming in natural water)
 - Other lifeways.

For convenience, we include a graphic that depicts many of these exposures.

EPA's SACC, in its report on the HBCD and 1,4-dioxane draft risk evaluations, strongly agreed with NTTC that EPA must consider all exposure routes and give "special consideration to specific populations (e.g., tribal, arctic inhabitants, etc.) who depend on fish as a major source of food because of cultural considerations and provide some quantitative sense of how much extra risk exists for these populations. In considering special and susceptible population exposures, more consideration needs to be given to...tribal, ethnic and other subpopulations that depend heavily on potentially contaminated foods, such as Native American subsistence fishers". The SACC also recommended that "the context of the assessment would be improved by including a graphic similar to the one presented by the National Tribal Toxics Council at the public meeting, that illustrates exposure routes for potentially sensitive or highly exposed populations" (reference to the conceptual model above).

TSCA states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." In its draft risk evaluation, EPA limited its analysis to only half of its own subpopulation definition. EPA discussed whether people might have higher susceptibility to NMP but, other than the consideration of worker, ONU, and consumer exposures, EPA did not consider whether any subpopulations might face greater risk due to greater exposure (p. 282; p. 197). EPA must consider and analyze each of these types of subpopulations.

EPA must analyze those potentially exposed or susceptible subpopulations that face greater exposure due to their proximity to conditions of use, particularly disposal. In the Problem Formulation for NMP, EPA acknowledged that it should analyze these vulnerable populations by



identifying “Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, use or *disposal sites*)” as a “potentially exposed or susceptible subpopulation that EPA expects to consider in the risk evaluation due to their greater exposure” (italics added, Page 37). In the draft risk evaluation for NMP however, EPA did not identify populations living or working near a disposal site as potentially exposed or susceptible subpopulations (p. 163) and did not provide any analysis of whether they are at a greater risk due to higher exposure. Many tribal communities live in close proximity to a disposal site or a transfer station. Three quarters of tribal communities in Alaska have residents living within 1 mile of unlined landfills that are open access and typically practice waste burning without emissions treatment or waste separation as a volume reduction management technique. Drinking water sources and primary diet sources for these close-set communities are also typically proximate. Workers work at the site, live near the site and eat and drink from sources near the site. The public uses the site, lives near the site and consumes food and water from near the site. The multiple exposure scenarios associated with proximity to unlined disposal site releases to environmental media must be analyzed for both individual exposures and the cumulative exposures tribal members face from their customary and traditional tribal lifeways (inhalation, dermal, ingestion). If these exposures are not analyzed, then no determination can

be made on the risks these vulnerable populations face. As part of this analysis, EPA should identify all populations living near disposal and other waste management sites as potentially exposed subpopulations. Groups living near National Priority List sites and proposed National Priority List sites should be included as well.

3. These exposures are not covered by other Environmental Statutes and should be evaluated.

a) General population

In this draft risk evaluation, EPA has excluded all risks the general population faces from exposures due to releases of NMP to land, air, and water, based on the assumption that other statutes adequately address these exposures. On page 21 of the draft risk evaluation for NMP, EPA states that “EPA is not including general population exposures in the risk evaluation for NMP. As explained in the Problem Formulation for the Risk Evaluation for NMP, general population exposures were determined to be outside the scope of the risk evaluation. EPA has determined that the existing regulatory programs and associated analytical processes adequately assess and effectively manage the risks of NMP that may be present in various media pathways (e.g. air, water, land) for the general population. For these cases, EPA believes that the TSCA risk evaluation should not focus on those exposure pathways, but rather on exposure pathways associated with TSCA conditions of use that are not subject to those regulatory processes, because the latter pathways are likely to represent the greatest areas of concern to EPA.” Yet, no analyses or data have been presented to show that other statutes are protective of the general population. For example, NMP is not currently regulated under the Safe Drinking Water Act. It is also not listed as a hazardous air pollutant under the Clean Air Act. That means that there is no federal limit for NMP levels in drinking water and that it is subject to only limited Clean Air Act regulations, which (unlike TSCA) do not encompass all known sources of the chemical and do not require the elimination of unreasonable risk. As the SACC stated in its report on the 1,4-dioxane risk evaluation, “if each program office of the EPA says others are assessing the risks and thus not including them in their assessment, the U.S. public will be left with no overall assessment of risks.” NTTC fully agrees. EPA should evaluate all known, intended, and reasonably foreseen exposures to a substance in its draft risk evaluations.

The SACC’s report on the 1,4-dioxane and HBCD draft risk evaluations stated that “several Committee members noted a concern on the exclusion of the general population and susceptible populations from the Problem Formulation under the assumption that other regulations (e.g. Clean Water Act, Clean Air Act, Safe Drinking Water Act) cover the pathways and noted this is counter to the state-of-the-art practice for risk assessment”. And yet, EPA has ignored those same exposures in the draft risk evaluations for both methylene chloride and NMP. TSCA defines conditions of use as “the circumstances” under which a chemical is “intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” EPA is thus required to evaluate all such risks, regardless of whether other statutes regulate them. The exclusion of known exposure pathways violates

both the intent and letter of TSCA. In a recent decision on EPA's TSCA risk evaluation rule, the Ninth Circuit Court of Appeals ruled that EPA is unambiguously not granted the discretion "to exclude conditions of use, or their associated exposures and risks, from TSCA risk evaluations".

One issue with relying on other environmental statutes is that TSCA tasks EPA with addressing human and environmental health risks, while other environmental statutes may have standards that are not health-based and are different from those under TSCA. TSCA section 6(b)(4)(A) states: "The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." Many statutes require EPA to consider factors such as cost and feasibility when setting their standards—factors that TSCA explicitly forbids EPA from considering when evaluating risks. EPA is the agency that is mandated to administer TSCA and relying on other statutes that are presumably protective completely ignores significant releases and the resulting exposure scenarios, which is clearly not the intent of TSCA. The releases and exposures EPA is ignoring are far from trivial. EPA includes data on releases of NMP to air, water, and land for years 2015-2017 on page 30 of the draft risk evaluation, showing that over 9,500,000 lbs/year are released into the environment. EPA's approach effectively reduces this quantity to zero.

Furthermore, NTTC takes this opportunity to point out that environmental statutes do not guarantee protection from exposures, particularly in the case of tribes, who may be disproportionately impacted. A non-exhaustive list of examples includes the 229 Tribes in Alaska that have landfills in compliance with RCRA, but that are unlined, use no cover material, allow open burning, with no monitoring or leachate collection. Under the Safe Drinking Water Act and the Clean Water Act, multiple tribes use individual groundwater well systems that are not regulated or monitored and have members on remote systems that are not POTWs due to the system size. Multiple tribes live in rural areas and use open barrels for burning. Burnboxes, which are open steel containers designed to accept an entire community's wastestream, are employed in Alaska for waste disposal and allowed under a special rule of the Clean Air Act. Burning on the ground is also practiced as a locally authorized waste management practice for a substantial number of Alaska tribes. Clearly, tribes experience exposures even where responsibility rests on other environmental statutes, and NTTC strongly urges EPA to comply with their statutory obligation to consider all exposures, particularly for susceptible and highly exposed populations, such as tribes.

NTTC has expressed concern at the paucity of data on tribal risks, as well as the observation that tribal people are underrepresented or absent from EPA's risk evaluations and proposed actions. It is well documented in the scientific literature that Native Americans experience significant health disparities from the general population and the practice of leaving them out of any protections can only contribute to further health disparities. NTTC has in the past provided detailed information to EPA on the chronic exposures tribal people experience. In order to protect tribal communities, the unique tribal lifeways and exposures, including those

from disposal of products containing toxic chemicals in open dumps that are unlined and that practice open burning of wastes, have to be considered by EPA.

b) Worker population

In this draft risk evaluation, EPA has significantly underestimated occupational exposures, both by assuming proper PPE use (e.g., the proper use of gloves is assumed for every commercial use of NMP) and by not considering aggregate exposures workers face for multiple conditions of use.

In this draft risk evaluations, EPA evaluated the risks of NMP to workers with and without PPE use; however, the determination whether risks were unreasonable was made assuming glove use. No data or other evidence is presented to support this assumption and instead it is stated that “Overall, EPA understands that workers may potentially wear gloves but does not know the likelihood that workers wear gloves of the proper type and have training on the proper usage of gloves” (page 68). In its report on the 1,4-dioxane and HBCD risk evaluations, the SACC warned that improper glove use “could actually lead to heightened exposures” due to “contamination of the interior of the glove”. Therefore, if EPA does not know whether gloves are worn or whether workers have training on their proper use, EPA cannot assume proper glove use in its risk determinations.

Furthermore, the SACC expressed concern that, even if PPE use is assumed for larger, industrial facilities, smaller facilities are much less likely to require routine and effective use of PPE or to employ engineering controls, such as closed systems. Smaller businesses and facilities are the norm in Indian Country, including Alaska Native villages, and they are subject to OSHA exemptions to reporting and inspection requirements. Self-employed workers are also exempt from many OSHA requirements and self-employment is common in tribal communities. For example, in rural Alaska non-hub communities, where the majority of Alaska’s federally recognized tribes live, OSHA will only provide assistance and compliance visits if three separate entities request them. Most of rural Alaska’s communities do not have three entities to which the workplace exposures discussed in the draft risk evaluation would be relevant. For accurate risk characterization of tribal members, NTTC would like to see a risk determination for workers and ONUs, both self-employed and in small businesses, that incorporates OSHA’s exemptions and practical exceptions. In these communities, take-home exposures are also very likely.

Moreover, as already discussed above, EPA has ignored all non-occupational baseline exposures workers experience by excluding all exposures via environmental releases to air, water, and land. NTTC believes that EPA cannot ignore the risks to individuals, even if EPA chooses to assume that other environmental statutes are protective and does not consider risks from environmental releases of NMP.

Another way EPA has underestimated the risk to workers in this draft risk evaluation is by not considering the combined risks from inhalation and dermal exposures for multiple conditions of use. Aggregate exposures for each condition of use were evaluated but EPA states that “While

this assessment evaluates specific COUs based on exposure estimates that incorporate multiple routes of exposure, it does not consider the potential for aggregate exposures from multiple conditions of use. For example, it does not evaluate the aggregate risk to individuals exposed via occupational and consumer uses. This could result in an underestimate of risk” (Page 283). To accurately assess overall exposure to NMP, EPA should prepare an exposure assessment that examines aggregate exposure. Aggregate exposure is defined as “the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways” (40 C.F.R. § 702.33). Such an exposure assessment should combine exposures from the inhalation and dermal pathways, including the baseline exposures mentioned above, under all conditions of use.

4. Risks from aggregate and cumulative exposures should be evaluated.

NTTC notes that to fulfill the intent of Congress, EPA must evaluate the true risk of a chemical in commerce, and therefore must consider aggregate and cumulative exposures for all potentially exposed populations. Assessment of risk should mirror the real world so that the public is truly protected by agency risk management decisions. For example, in tribal communities, a substantial number of residents have multiple jobs and live near their community facilities, including disposal facilities. A single person may be a landfill worker, an occupational bystander, a near-facility general population, as well as a consumer. They will likely derive their food and water, including untreated water, near-source. Such scenarios are prevalent for tribal landfill workers because tribal members tend to live, work, recreate, and subsist within the lands upon which their ancestors did the same. The resulting multiple exposures should be considered in aggregate, and in cumulative. Tribal peoples tend to reside on these lands for their entire lifetime because this physical connection is paramount to tribal peoples’ well-being and what it means to be a tribal person.

5. Legacy use must be included.

On November 15, 2019, the Ninth Circuit Court of Appeals released its decision in the challenge to the TSCA risk evaluation and prioritization rules that EPA can no longer exclude “legacy” chemical uses from a risk evaluation, nor can it exclude any conditions of use from consideration. It also affirmed that “TSCA’s definition of ‘conditions of use’ clearly includes uses and future disposals of chemicals”.

Legacy use of products containing NMP was not considered in this draft risk evaluation. In order to accurately address the risks NMP may pose to human health and the environment, the use and unsafe disposal of consumer products containing it need to be evaluated. Not considering legacy use, and the risks it poses, disproportionately affects tribes’ exposures, in this case due to the unique disposal circumstances on tribal lands and in tribal communities. NTTC strongly urges EPA to consider the impacts of legacy use of NMP on tribal populations.

We look forward to the Agency's written response to these comments within 90 days. Should you or your staff have questions or comments regarding our letter, please contact myself, Dianne Barton, NTTC Chair, at (503) 731-1259 / bard@critfc.org or Fred Corey, NTTC Co-Chair, at (207) 764-7765 / fcory@micmac-nsn.gov.

Sincerely,

A handwritten signature in cursive script that reads "Dianne C. Barton".

Dianne C. Barton, Ph.D.
Chair, National Tribal Toxics Council